Non-Technical Abstract

Many types of cancer are resistant to available medical treatments including drugs, chemotherapy, surgery and radiation, alone or in combinations. The intent of the proposed treatment is to evaluate the safety and immune response of direct injection of Leuvectin in the prostate. In this study, an experimental procedure will be conducted, which will attempt to fight cancer by injecting genetic material, DNA, directly into the prostate. The DNA is mixed with lipid to form a complex for injection. DNA will be taken into cells causing them to produce and secrete a protein that stimulates the immune system. This protein, called Interleukin-2 (IL-2), causes cells which secrete it, to recruit immune cells to the tumor site, which may lead to tumor reduction or eradication.

In this study, we will attempt to learn the range of safe and effective doses of the DNA/lipid complex. In addition, we will attempt to learn the effects of injection into the tumor prior to tumor resection. Increasing amounts of this complex will be administered in two doses, directly into the prostate tumor. Patients will then undergo radical prostatectomy or biopsy of recurrent disease. This treatment may provide a potent therapeutic effect in cancer, based on a well-characterized protein in a potentially toxicity-free delivery mechanism.

The IL-2 protein has been approved by FDA for cancer therapy in renal cell carcinoma, and is undergoing advanced clinical evaluation for treatment of melanoma. The proposed study enables local production of IL-2 *in situ* to attract and stimulate the immune response required for tumor regression.